EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, Plaintiff, v. FOOD & DRUG ADMINISTRATION; DR. STEPHEN M. HAHN, Commissioner of Food & Drugs, in his official capacity; BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY; GARY L. DISBROW, Ph.D., Acting Director, Biomedical Advanced Research & Development Authority, in his official capacity; DEPARTMENT OF HEALTH & HUMAN SERVICES; and ALEX AZAR, Secretary of Health & Human Services, in his official capacity, Defendants.	)	No. 1:20-cv-00493-RJJ-SJB Hon. Robert J. Jonker

DECLARATION BY JANE ORIENT, M.D.

I, Jane Orient, M.D., hereby declare that:

1. I am over the age of 21 years and competent to make this declaration pursuant to 28 U.S.C. § 1746. I have not been convicted of a felony or a crime of dishonesty.

2. I graduated with a degree in medicine from the Columbia University College of Physicians & Surgeons, and for decades have successfully practiced in internal medicine in Tucson, Arizona.

3. I am the author of *Sapira's Art & Science Of Bedside Medical Diagnosis*, including its 2nd through its current 5th editions, which is a comprehensive textbook on clinical examination.

4. I am the executive director of Plaintiff Association of American Physicians & Surgeons in this action.

5. I am familiar with the prevalence of prescribing medications, which have been approved by the Food & Drug Administration, for unapproved or "off-label" uses.

6. Physicians may lawfully prescribe an FDA-approved drug for off-label uses, which account for a significant percentage of all prescriptions.

7. Once a medication is approved by the FDA for any purpose, it is then considered to be a safe medication, and approval by the FDA for additional purposes, including off-label uses, is not commonly sought or granted.

8. For older, generic medication such as hydroxychloroquine (HCQ), on which any patent rights have long since expired, there is an insufficient financial incentive to fund expensive studies to seek approval by the FDA for off-label uses.

9. It typically costs many millions of dollars to do double-blind studies of medication in order to obtain approval by the FDA, and once a medication is approved it would be a waste of resources to incur such substantial expenses to obtain a redundant second approval, for a new purpose such as an off-label use.

10. Instead, physicians commonly prescribe medication for off-label uses such as treating an illness different from the purpose for which the medication was originally approved. This off-label prescribing is done based on the experience of the physician, articles in the medical literature, or merely communications of anecdotal success with the medication.

11. Indeed, the FDA itself admits that it does not have legal authority to practice medicine, and it does not generally forbid off-label uses of medication that it has previously approved without limitation as it has done for HCQ.

12. HCQ was approved as safe by the FDA in 1955 and has a 65-year track record of safety ever since.

13. HCQ is very inexpensive, costing less than a dollar per dose, in contrast with other medications costing hundreds of dollars per dose.

14. Multiple published studies show the safety of administering HCQ to patients who have COVID-19.

15. Multiple published studies show the effectiveness of HCQ with respect to COVID-19 when administered as an early treatment or prophylaxis.

16. Anti-viral medications, which HCQ is, generally need to be taken as early in the progression of a disease as possible.

17. COVID-19, which is caused by a virus, would therefore presumably be most effectively treated with medication taken early in the progression of the disease, or for prophylaxis.

18. HCQ has been used successfully as a prophylaxis for travelers to areas where malaria is prevalent, and I am not aware of any reason why it might not be effective as a prophylaxis for COVID-19.

19. Indeed, a reported study from India where HCQ has been given as prophylaxis to health care workers in contact with COVID-19 demonstrates effectiveness by HCQ in reducing the contagion from COVID-19.

20. Reports from multiple countries show a significantly reduced overall mortality from COVID-19 when HCQ is used early rather than withheld as the FDA has been doing with respect to the Strategic National Stockpile (SNS).

21. Many patients have avoided congregating with others, whether at a religious service, an AAPS meeting, or a political gathering, out of fear of contracting COVID-19 without the benefit of access to prophylactic or early treatment.

22. There is no approved vaccine for COVID-19. The promise of a vaccine by the end of 2020 or early 2021 requires shortcutting safety testing, which by its very nature requires more time. Indeed, it is possible that no safe and effective vaccine for COVID-19 will ever be developed.

23. The FDA cited flawed studies as the basis for its revoking its Emergency Use Authorization (EUA).

24. One study on which the FDA was perhaps initially relying was retracted by the British medical journal *Lancet*, because of flawed data not detected in a faulty pre-publication review.

25. Another flawed study relied upon by the FDA in revoking its EUA consisted of the administration of HCQ an average of 16.6 days into the progression of the disease, which is far too late for an anti-viral medication to succeed against a virus.

26. The limitation in the EUA to administer HCQ from the SNS only after a patient has been hospitalized is likewise too late for an anti-viral medication such as HCQ to be most effective.

27. Concerning the unjustified condition in the EUA of the availability of a clinical trial, typically half the patients in a clinical trial are given a placebo as a control against which to compare the effectiveness of a medication. The FDA's requirement that COVID-19 patients participate in a clinical trial is irrational because half of such patients would typically not receive the medication that way.

28. In addition, studies show that minorities are underrepresented in clinical trials and thus could have less access to HCQ under the requirement in the

EUA forbidding use of HCQ for patients who are not enrolled in an available clinical trial.

29. Several widely publicized studies purporting to show risks and benefits have used HCQ in populations which are unlikely to benefit, with inappropriately high doses given to them to their predictable detriment.

30. Allegations of harm from HCQ are based on publications that used potentially toxic doses, apparently and erroneously ignoring the long half-life of HCQ which makes cumulative dosage critical.

31. As to the SNS, medication degrades over time, particularly in hot temperatures. The likelihood of the HCQ medication in the SNS never being timely used and even being discarded increases with each passing day.

32. Patients from many states have contacted us at AAPS and described difficulties in obtaining HCQ. Their local physicians and pharmacists are constrained in reliance on the FDA. The EUA, and the FDA's continuing restrictions on the SNS after its revocation of the EUA, give the impression that the FDA has not fully approved HCQ when in fact the FDA did so in 1955.

33. On June 16, 2020, Defendant FDA issued this false statement:

> FDA revoked the EUA for CQ and HCQ after determining that it is unlikely that CQ and HCQ may be effective in treating COVID-19.

Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate, at 2

(June 16, 2020). To the best of my knowledge the FDA has not made any such valid determination based on sound data with respect to HCQ.

34. Similarly, on the same day Defendant HHS issued this misleading statement:

> Now, hydroxychloroquine sulfate and chloroquine phosphate can only be used for the treatment of COVID-19 as part of an ongoing clinical trial.

ASPR's Portfolio of Investigational Medical Countermeasures being used to treat COVID-19 (as issued by Defendant HHS on June 16, 2020). In fact, Defendant HHS thereby misleads the public by improperly stating that HCQ can only be used for the treatment of COVID-19 in clinical trials.

35. Defendants HHS and FDA have arbitrarily singled out HCQ for unjustified disparagement and exclusion. Due the novelty of COVID-19, all treatments for it are outside of the purposes of prior FDA approvals.

36. Americans are being denied benefits available to people in other countries, such as in Brazil with its recent use of HCQ from the (U.S.) SNS, and many Americans are being hospitalized or dying because of denial of access to the HCQ in the SNS and the FDA's arbitrary restrictions on use of HCQ.

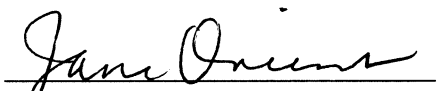
37. There are virtually no treatments feasible for out-patients, other than HCQ, which are now being investigated; virtually all the alternatives are drugs for inpatient use on hospitalized patients.

38. Physicians, including members of AAPS, have encountered unprecedented and irrational interference in prescribing HCQ with respect to COVID-19.

39. The FDA's arbitrary restrictions on HCQ as initially set forth in its EUA have even caused some studies of HCQ to be arbitrarily stopped.

40. Because of barriers arbitrarily created by the FDA to impede access to HCQ, AAPS members and most Americans are being unjustifiably denied access to this safe, effective, and inexpensive treatment for COVID-19.

I declare under penalty of perjury that the foregoing is true and correct. Executed on June 22, 2020.



Jane Orient, M.D.